

CAPITAL NEUROSURGERY, INC.

Kenneth J. Rich, M.D.

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July 7<sup>th</sup>, 2000

Ms. Kathy Eberhart  
Food and Drug Administration  
Center for Biologics Evaluation and Research  
1404 Rockville Pike  
Suite 200 North  
Rockville, Maryland 20852-1448

Dear Ms. Eberhart:

I will be unable to attend the open public meeting regarding classifying human tissues as medical devices on August 2<sup>nd</sup> in Rockville, Maryland. I do, however, want to go on record as being very much against this. As a surgeon who uses among other human tissues cadaveric bone for spinal fusions, I can attest both personally and with the support of the literature that cadaveric bone is effective, useful, and safe. Clinical results have demonstrated that there is no difference in long-term outcome whether you use your own bone for spinal fusions or cadaveric bones for spinal fusions of most sorts. There is not a problem here with transmission of AIDS, cancer, Hepatitis, or other medical diseases. The incidence of that with human tissue such as cadaveric bone is zero or next to zero. The pain and suffering the patient is put through when we have to harvest bone from their own hip to perform spinal fusions is quite extraordinary. Most patients will tell you that's the most painful part of a spinal fusion procedure. We need safety in medicine, but we will not accomplish this by taking human tissues such as cadaveric bone and making them apply for FDA approval for medical devices. We're not having a problem with cadaveric bone and it should be left alone. I can not stress this strongly enough to limit our access to cadaveric bone for spinal fusions while we undergo FDA testing and approval would be a very huge disservice to a large number of patients who would suffer

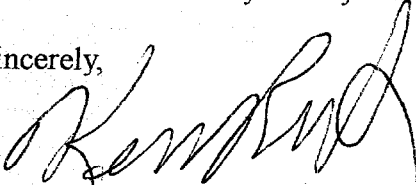
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Ms. Kathy Eberhart  
July 7<sup>th</sup>, 2000

unnecessarily because of your actions. I do not think anyone believes that's the purpose of the FDA. Thank you very much for your attention to this matter.

Sincerely,

A handwritten signature in black ink, appearing to read 'Ken Rich', written over the word 'Sincerely,'.

Kenneth J. Rich, M.D.

KJR/mmk

dd: 07-07-00

dt: 07-10-00

cc: David Price, Representative

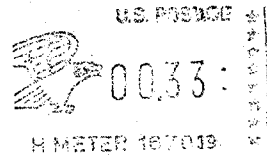
cc: Jesse A. Helms, Senator

cc: John Edwards, Senator

cc: C. Randal Mills, Ph.D.

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